

## NATURAL HEALTH PRODUCT

### CASCARA SAGRADA – *FRANGULA PURSHIANA*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

#### Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicant’s discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

**Date** October 30, 2018

#### Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Frangula purshiana</i>	<ul style="list-style-type: none"> <li>▶ Bitter bark</li> <li>▶ California buckthorn</li> <li>▶ Cascara</li> <li>▶ Cascara buckthorn</li> <li>▶ Cascara sagrada</li> <li>▶ Chittambark</li> <li>▶ Chitem bark</li> <li>▶ Sacred bark</li> <li>▶ Western buckthorn</li> </ul>	<i>Frangula purshiana</i>	Aged bark	Dried

References: Proper name: USDA 2018; Common name: McGuffin et al. 2000; Source information: Wichtl 2004, Blumenthal et al. 2000.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.



Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

### Use(s) or Purpose(s)

- ▶ (Traditionally used in Herbal Medicine as a) stimulant laxative (Williamson 2003; Blumenthal et al. 2000; Moerman 1998; Felter and Lloyd 1898).
- ▶ (Used in Herbal Medicine for the) short-term relief of occasional constipation (EMEA 2007; Mills and Bone 2005; WHO 2002).
- ▶ (Used in Herbal Medicine to) promote(s) bowel movement (by direct action on the large intestine) (EMEA 2007; Sweetman 2007; Blumenthal et al. 2000).

The following combined use(s) or purpose(s) is/are also acceptable:

(Used in Herbal Medicine as a) stimulant laxative to promote bowel movement and short-term relief of occasional constipation (EMEA 2007; Sweetman 2007; Mills and Bone 2005; Williamson 2003; WHO 2002; Blumenthal et al. 2000; Moerman 1998; Felter and Lloyd 1983).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### Dose(s)

#### Subpopulation(s)

Adolescents 12 to 17 years and Adults 18 years and older (EMEA 2007; Mills and Bone 2005; ESCOP 2003; Berardi et al. 2002)

#### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

0.25-3 grams of dried aged bark, per day (Mills and Bone 2005, ESCOP 2003; Williamson 2003; WHO 2002; Blumenthal et al. 2000; Bradley 1992).

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

10-30 milligrams of hydroxyanthracene derivatives (calculated as cascarioside A), per day (EMEA 2007; Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000).

#### Direction(s) for use



- ▶ Take two to three times per week. If results are not observed, the frequency of use may be increased up to once daily (EMEA 2007).
- ▶ Take a single dose at bedtime (Bradley 1992).
- ▶ Take a few hours before or after taking other medications or natural health products (Brinker 2010; Repchinsky 2008).
- ▶ Allow at least 6 to 12 hours for laxative effect to occur (Berardi et al. 2002).

*For products which provide a dosage range (Optional)*

The correct individual dose is the smallest required to produce a soft-formed stool (EMEA 2007; McGuffin 1997).

### **Duration(s) of use**

Consult a health care practitioner/health care provider/health care professional/doctor/ for use beyond 7 days (Berardi et al. 2002).

### **Risk information**

#### **Caution(s) and warning(s)**

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have kidney disorder, faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever (Brinker 2010; EMEA 2007; WHO 2002).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications, thiazide diuretics, corticosteroids, licorice root or other medications or health products which may aggravate electrolyte imbalance (Brinker 2010; EMEA 2007; WHO 2002; Blumenthal et al. 2000).
- ▶ Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhoea (EMEA 2007; WHO 2002; Blumenthal et al. 2000).

#### **Contraindication(s)**

- ▶ Do not use this product if you have abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease such as Crohn's disease or ulcerative colitis, abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes or diarrhoea (Brinker 2010; EMEA 2007; WHO 2002; McGuffin 1997).
- ▶ Do not use this product if you are pregnant or breastfeeding (Brinker 2010; EMEA 2007; Blumenthal et al. 2000).



### **Known adverse reaction(s)**

Stop use if hypersensitivity/allergy occurs (EMA 2007).

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **Storage conditions**

No statement required.

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.
- ▶ Bark must be dried and aged for a minimum of one year or heated and dried to induce artificial aging to allow oxidation of the anthrones. For example, the bark may be heated in hot air at 80-100°C for several hours (Wichtl 2004; Blumenthal et al. 2000).

### **References cited**

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. 2002. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13<sup>th</sup> edition. Washington (DC): American Pharmaceutical Association.

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications.

Bradley PR, editor. 1992. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

EMA 2007. European Medicines Agency. Community Herbal Monograph on *Rhamnus*



*Purshianus* D.C., cortex (on line). London (UK): EMEA Committee on Herbal Medicinal Products (HMPC), 7 September 2007. [Accessed 2018 August 15]. Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Herbal\\_-\\_Community\\_herbal\\_monograph/2009/12/WC500018424.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2009/12/WC500018424.pdf)

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme.

Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 1, 18<sup>th</sup> edition. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original].

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. Herbs of Commerce, 2<sup>nd</sup> edition. Silver Spring (MD): American Herbal Products Association.

Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone.

Moerman DE. 1998. Native American Ethnobotany. Portland (OR): Timber Press.

Repchinsky C, editor. 2008. Compendium of Pharmaceuticals and Specialties. The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association.

Sweetman SC, editor. 2007. Martindale: The Complete Drug Reference, 35<sup>th</sup> edition. London (UK): Pharmaceutical Press.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. *Frangula purshiana* (DC.) J.G. Cooper. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2018 August 15]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)

WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 2. Geneva (CHE): World Health Organization.

Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3<sup>rd</sup> edition. Stuttgart (D): Medpharm GmbH Scientific Publishers.

Williamson EM. 2003. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (UK): The C.W. Daniel Company Limited.

## References reviewed

Barnes J, Anderson LA, Philipson JD. 2002. Herbal Medicines: A Guide for Healthcare



- Professionals, 2<sup>nd</sup> edition. London (UK): The Pharmaceutical Press.
- BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medicine Association.
- BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association.
- Ellingwood F. 1983. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications [Reprint of 1919 original].
- FDA 1985: United States Food and Drug Administration. Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph. Proposed Rules sections 334.10 and 334.52. Federal Register Volume 50, Number 10, Tuesday, January 15, 1985. [Accessed 2008 July 31]. Available from:  
[http://www.fda.gov/cder/otcmonographs/category\\_sort/laxative.htm](http://www.fda.gov/cder/otcmonographs/category_sort/laxative.htm)
- Gruenwald J, Bendler T, Jaenicke C, editors. 2004. PDR for Herbal Medicines, 3<sup>rd</sup> edition. Montvale (NJ): Medical Economics Company.
- HC 1997. Health Canada. TPD/NHPD Category IV Labelling Standard, Stimulant Laxatives [online]. Ottawa (ON): Therapeutic Products Directorate, Health Canada. [Accessed 2008 August 26]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label-etiquet-pharm/laxstimu-eng.php>
- HC 1994. Health Canada. TPD/NHPD Category IV Labelling Standard, General Laxatives [online]. Ottawa (ON): Therapeutic Products Directorate, Health Canada. [Accessed 2008 August 26]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label-etiquet-pharm/laxat-eng.php>
- Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.
- Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone.
- Pray WS. 2006. Non-Prescription Product Therapeutics, 2<sup>nd</sup> edition. New York (NY): Lippincott Williams & Wilkins
- Remington JP, Woods HC, editors. 1918. The Dispensary of the United States of America [online] 20<sup>th</sup> edition. Abridged; botanicals only. Bisbee (AZ): Scanned by Michael Moore, director, The Southwest School of Botanical Medicine. [Accessed 2008 August 2]. Available from: <http://www.swsbm.com/Dispensary/USD-1918-complete.pdf>
- Repchinsky 2002: Canadian Pharmacists Association. Patient Self-Care. Helping Patients Make Therapeutic Choices. Ottawa (ON): Canadian Pharmacists Association.
- Wiersema J, León B. 1999. World Economic Plants: A Standard Reference. Boca Raton (FL):



Health  
Canada

Santé  
Canada

CRC Press LLC